CLAIMS

What is claimed is:

1. A method for aiding in a diagnosis of head and neck squamous cell carcinoma in a patient, comprising:

(a) obtaining a body fluid sample from a patient suspected of suffering from head and neck squamous cell carcinoma;

(b) detecting at least one protein biomarker in said sample, said protein biomarker selected from the group consisting of protein biomarkers having a molecular weight of about 2778 ± 5.6, 2951 ± 5.9, 3772 ± 7.5, 3888 ± 7.8, 4181 ± 8.4, 4464 ± 8.9, 5064 ± 10.1, 5078 ± 10.2, 5242 ± 10.5, 5335 ± 10.7, 5363 ± 10.7, 5544 ± 11.1, 5905 ± 11.8, 5920 ± 11.8, 6110 ± 12.2, 7764 ± 15.5, 7805 ± 15.6, 7830 ± 15.7, 7920 ± 15.8, 7971 ± 15.9, 8928 ± 17.9, 9094 ± 18.1, 9134 ± 18.3, 9181 ± 18.4, 9287 ± 18.6, 9416 ± 18.8, 10264 ± 20.5, 10843 ± 21.7, 11722 ± 23.4, 11922 ± 23.8, 13350 ± 26.7, 13881 ± 27.8, 14687 ± 29.4, and 15139 ± 30.3 Daltons;

(c) wherein said detecting of said at least one protein biomarker is correlated with a diagnosis of head and neck squamous cell carcinoma in said patient.

2. The method of claim 1, wherein said detection step further comprises identifying the differential expression of said at least one protein biomarker.

3. The method of claim 1, wherein the correlation takes into account the presence or absence of the said at least one protein biomarker in the sample and the frequency of detection of the same said at least one protein biomarker in a control.

4. The method of claim 3, wherein the correlation further takes into account the quantity of said at least one protein biomarker in the sample compared to a control quantity of the said at least one protein biomarker.

5. The method of claim 1, wherein at least one protein biomarker is selected from the group consisting of the about 5064 ± 10.1, 13881 ± 27.8, and 15139 ± 30.3 Dalton biomarkers.

6. The method of claim 5, wherein said method comprises determining the quantity of the about 5064 ± 10.1, 13881 ± 27.8, and 15139 ± 30.3 Dalton biomarkers.

7. The method of claim 1, wherein at least one protein biomarker is selected from the group consisting of the about 5064 ± 10.1, 2778 ± 5.6, 4464 ± 8.9, and 3772 ± 7.5 Dalton biomarkers.

8. The method of claim 7, wherein said method comprises determining the quantity of the about 5064 ± 10.1, 2778 ± 5.6, 4464 ± 8.9, and 3772 ± 7.5 Dalton biomarkers.

9. The method of claim 1, wherein at least one protein biomarker is selected from the group consisting of the about 5064 ± 10.1, 5242 ± 10.5, 13881 ± 27.8, and 15139 ± 30.3 Dalton biomarkers.

10. The method of claim 9, wherein said method comprises determining the quantity of the about 5064 ± 10.1, 5242 ± 10.5, 13881 ± 27.8, and 15139 ± 30.3 Dalton biomarkers.

11. The method of claim 1, wherein said detecting at least one protein biomarker is performed by mass spectrometry.

12. The method of claim 11, wherein said mass spectroscopy is laser desorption mass spectroscopy.

13. The method of claim of claim 12, wherein said mass spectroscopy is surface enhanced laser desorption/ionization mass spectroscopy.

14. The method of claim 13, wherein the laser desorption/ionization mass spectroscopy includes:

(a) providing a substrate comprising an adsorbent attached thereto;

(b) contacting the test sample with the adsorbent;

(c) desorbing and ionizing the biomarkers from the substrate; and

(d) detecting the desorbed/ionized biomarkers with a mass spectrometer.

15. The method of claim 14, further comprising purifying the test sample prior to contacting the sample with the adsorbent.

16. The method of claim 1, wherein said detecting at least one protein biomarker in a test sample from a subject is performed by immunoassay.

17. The method of claim 16, wherein said immunoassay is an enzyme immunoassay.

18. The method of claim 1, wherein the body fluid is blood serum.

19. The method of claim 1, wherein the body fluid is selected from the group consisting of seminal fluid, seminal plasma, saliva, blood, lymph fluid, lung/bronchial washes, mucus, feces, nipple secretions, sputum, tears, or urine.

20. The method of claim 1, wherein two to twenty biomarkers are detected.

21. The method of claim 1, wherein said method comprises:

(a) detecting the presence or absence of protein biomarkers having a molecular weight selected from the group consisting of about 5064 ± 10.1, about 13881 ± 27.8, and about 15139 ± 30.3 Daltons; and

(b) correlating the detection with a probable diagnosis of head and neck squamous cell carcinoma.

22. The method of claim 21, wherein the presence or absence of the protein biomarker having a molecular weight of about 5064 ± 10.1 Daltons is detected.

23. The method of claim 21, wherein the presence or absence of the protein biomarker having a molecular weight of about 5064 ± 10.1 and about 13881 ± 27.8 Daltons is detected.

24. The method of claim 21, wherein the presence or absence of the protein biomarker having a molecular weight of about 5064 ± 10.1, about 13881 ± 27.8, and about 15139 ± 30.3 Daltons is detected.

25. The method of claim 21, wherein said detecting is performed by mass spectroscopy.

26. The method of claim 25, wherein said mass spectroscopy is laser desorption mass spectroscopy.

27. The method of claim 26, wherein said mass spectroscopy is surface enhanced laser desorption/ionization mass spectroscopy.

28. The method of claim 27, wherein the laser desorption/ionization mass spectroscopy includes:

(a) providing a substrate comprising an adsorbent attached thereto;

(b) contacting the test sample with the adsorbent;

(c) desorbing and ionizing the biomarkers from the substrate; and

(d) detecting the desorbed/ionized biomarkers with a mass spectrometer.

29. The method of claim 28, further comprising purifying the test sample prior to contacting the test sample with the adsorbent.

30. The method of claim 21, wherein said detecting is performed by an immunoassay.

31. The method of claim 30, wherein said immunoassay is an enzyme immunoassay.

32. A kit comprising a substrate comprising an adsorbent attached thereto, wherein the adsorbent is capable of retaining at least one protein biomarker selected from the group consisting of about 5064 ± 10.1, 13881 ± 27.8, and 15139 ± 30.3 Daltons.

33. The kit of claim 32, wherein the substrate is a probe adapted for use with a gas phase ion spectrometer, said probe having a surface onto which the adsorbent is attached.

34. The kit of claim 32, wherein the adsorbent is a metal chelate adsorbent.

35. The kit of claim 32, wherein the adsorbent comprises a cationic group.

36. The kit of claim 32, wherein the substrate comprises a plurality of different types of adsorbent.

37. The kit of claim 32, wherein the adsorbent is an antibody that specifically binds to the biomarker.

38. The kit of claim 32, wherein the kit further comprises an eluant wherein the biomarker is retained on the adsorbent when washed with the eluant.

39. A kit comprising a substrate comprising an adsorbent attached thereto, wherein the adsorbent is capable of retaining at least one protein biomarker selected from the group consisting of about 2778 ± 5.6, 2951 ± 5.9, 3772 ± 7.5, 3888 ± 7.8, 4181 ± 8.4, 4464 ± 8.9, 5064 ± 10.1, 5078 ± 10.2, 5242 ± 10.5, 5335 ± 10.7, 5363 ± 10.7, 5544 ± 11.1, 5905 ± 11.8, 5920 ± 11.8, 6110 ± 12.2, 7764 ± 15.5, 7805 ± 15.6, 7830 ± 15.7, 7920 ± 15.8, 7971 ± 15.9, 8928 ± 17.9, 9094 ± 18.1, 9134 ± 18.3, 9181 ± 18.4, 9287 ± 18.6, 9416 ± 18.8, 10264 ± 20.5, 10843 ± 21.7, 11722 ± 23.4, 11922 ± 23.8, 13350 ± 26.7, 13881 ± 27.8, 14687 ± 29.4, and 15139 ± 30.3 Daltons.

40. The kit of claim 39, wherein the substrate is a probe adapted for use with a gas phase ion spectrometer, said probe having a surface onto which the adsorbent is attached.

41. The kit of claim 39, wherein the adsorbent is a metal chelate adsorbent.

42. The kit of claim 39, wherein the adsorbent comprises a cationic group.

43. The kit of claim 39, wherein the substrate comprises a plurality of different types of adsorbent.

44. The kit of claim 39, wherein the adsorbent is an antibody that specifically binds to the biomarker.

45. The kit of claim 39, wherein the kit further comprises an eluant wherein the biomarker is retained on the adsorbent when washed with the eluant.

46. A method of using a plurality of classifiers to make a probable diagnosis of head and neck squamous cell carcinoma or a negative diagnosis, comprising the steps of:

a) obtaining mass spectra from a plurality of samples from normal subjects and subjects diagnosed with head and neck squamous cell carcinoma; and;

b) applying a decision tree analysis to at least a portion of the mass spectra to obtain a plurality of weighted base classifiers comprising a peak intensity value and an associated threshold value, said values used in linear combination to make a probable diagnosis of at least one of head and neck squamous cell carcinoma and a negative diagnosis.

47. A computer program medium storing computer instructions therein for instructing a computer to perform a computer-implemented process of aiding in a diagnosis of benign prostate hyperplasia or prostate cancer, comprising:

(a) first computer program code means for detecting at least one protein biomarkers in a test sample from a subject, said protein biomarkers having a molecular weight selected from the group consisting of about 2778 ± 5.6, 2951 ± 5.9, 3772 ± 7.5, 3888 ± 7.8, 4181 ± 8.4, 4464 ± 8.9, 5064 ± 10.1, 5078 ± 10.2, 5242 ± 10.5, 5335 ± 10.7, 5363 ± 10.7, 5544 ± 11.1, 5905 ± 11.8, 5920 ± 11.8, 6110 ± 12.2, 7764 ± 15.5, 7805 ± 15.6, 7830 ± 15.7, 7920 ± 15.8, 7971 ± 15.9, 8928 ± 17.9, 9094 ± 18.1, 9134 ± 18.3, 9181 ± 18.4, 9287 ± 18.6, 9416 ± 18.8, 10264 ± 20.5, 10843 ± 21.7, 11722 ± 23.4, 11922 ± 23.8, 13350 ± 26.7, 13881 ± 27.8, 14687 ± 29.4, and 15139 ± 30.3 Daltons; and

(b) second computer program code means for correlating the detection with a probable diagnosis of benign prostate hyperplasia, prostate cancer or a negative diagnosis.

48. The medium of claim 47, wherein the at least one protein biomarker is the about 5064 ± 10.1 Dalton protein biomarkers.

49. The medium of claim 47, wherein the protein biomarkers are the about 5064 ± 10.1 and 13881 ± 27.8 Dalton biomarkers.

50. The medium of claim 47, wherein the protein biomarkers are the about 5064 ± 10.1, 13881 ± 27.8, and 15139 ± 30.3 Dalton biomarkers.

51. The method of claim 1, wherein the protein biomarker is about 5064 ± 10.1 Daltons.

52. The method of claim 51, wherein said method comprises determining the quantity of the 5064 ± 10.1 Dalton biomarker.

53. A method for aiding in a diagnosis of head and neck squamous cell carcinoma in a patient comprising:

(a) obtaining a body fluid sample from a patient suspected of suffering from head and neck squamous cell carcinoma;

(b) detecting, by surface enhanced laser desorption/ionization time of flight mass spectrometry (SELDI-TOF-MS), at least one protein biomarker in said sample, said protein biomarker selected from the group consisting of protein biomarkers having a molecular weight of about 5064 ± 10.1, 13881 ± 27.8, and 15139 ± 30.3 Daltons;

(c) wherein said detecting of said at least one protein biomarker is correlated with a diagnosis of head and neck squamous cell carcinoma in said patient.

54. A method for aiding in a diagnosis of head and neck squamous cell carcinoma in a patient comprising:

(a) obtaining a body fluid sample from a patient suspected of suffering from head and neck squamous cell carcinoma;

(b) detecting, by surface enhanced laser desorption/ionization time of flight mass spectrometry (SELDI-TOF-MS), at least one protein biomarker in said sample, said protein biomarker selected from the group consisting of protein biomarkers having a molecular weight of about 5064 ± 10.1, 2778 ± 5.6, 4464 ± 8.9, and 3772 ± 7.5 Daltons;

(c) wherein said detecting of said at least one protein biomarker is correlated with a diagnosis of head and neck squamous cell carcinoma in said patient.

55. A method for aiding in a diagnosis of head and neck squamous cell carcinoma in a patient comprising:

(a) obtaining a body fluid sample from a patient suspected of suffering from head and neck squamous cell carcinoma;

(b) detecting, by surface enhanced laser desorption/ionization time of flight mass spectrometry (SELDI-TOF-MS), at least one protein biomarker in said sample, said protein biomarker selected from the group consisting of protein biomarkers having a molecular weight of about 5064 ± 10.1, 5242 ± 10.5, 13881 ± 27.8, and 15139 ± 30.3 Daltons;

(c) wherein said detecting of said at least one protein biomarker is correlated with a diagnosis of head and neck squamous cell carcinoma in said patient.

56. A method for aiding in a diagnosis of head and neck squamous cell carcinoma in a patient comprising:

(a) obtaining a body fluid sample from a patient suspected of suffering from head and neck squamous cell carcinoma;

(b) detecting, by surface enhanced laser desorption/ionization time of flight mass spectrometry (SELDI-TOF-MS), at least one protein biomarker in said sample, said protein biomarker selected from the group consisting of protein biomarkers having a molecular weight of about 5064 ± 10.1, 5242 ± 10.5, 13881 ± 27.8, and 15139 ± 30.3 Daltons;

(c) wherein said detecting of said at least one protein biomarker is correlated with a diagnosis of head and neck squamous cell carcinoma in said patient.

57. A method for aiding in a diagnosis of head and neck squamous cell carcinoma in a patient comprising:

(a) obtaining a body fluid sample from a patient suspected of suffering from head and neck squamous cell carcinoma;

(b) detecting, by surface enhanced laser desorption/ionization time of flight mass spectrometry (SELDI-TOF-MS), a protein biomarker in said sample having a molecular weight of about 5064 ± 10.1 Daltons;

(c) wherein said detecting of said protein biomarker is correlated with a diagnosis of head and neck squamous cell carcinoma in said patient.

58. A method for aiding in a diagnosis of head and neck squamous cell carcinoma in a patient comprising:

(a) obtaining a body fluid sample from a patient suspected of suffering from head and neck squamous cell carcinoma;

(b) detecting, by surface enhanced laser desorption/ionization time of flight mass spectrometry (SELDI-TOF-MS), the quantity of a protein biomarker in said sample having a molecular weight of about 5064 ± 10.1 Daltons;

(c) wherein underexpression of said protein biomarker is correlated with a diagnosis of head and neck squamous cell carcinoma in said patient.